

THE TREATMENT OF COMPLETE HEART BLOCK WITH AN IMPLANTED, CONTROLLABLE PACEMAKER

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THE INCIDENCE of atrioventricular dissociation and Stokes-Adams seizures has been variously estimated. Rowe and White reviewed 160,000 electrocardiograms taken at the Massachusetts General Hospital from 1925 to 1955 and discovered 350 patients who showed complete atrioventricular dissociation. Penton, Miller, and Levine reported 251 cases of complete heart block during a 42 year period. In Rowe's series, Stokes-Adams syndrome occurred in 30 per cent of the patients, whereas Penton reported an incidence of 61 per cent. At Maimonides Hospital of Brooklyn, 44 cases of Stokes-Adams syndrome were seen during the 5 year period 1956 through 1960.

By far the most common cause of complete heart block in the older age group is coronary artery disease. There is an increasing number of patients who have permanent heart block subsequent to open heart surgery.

Since 1952 when Zoll first suggested the use of an external electric stimulator in the treatment of intractable, complete heart block, there has been increasing interest in this therapeutic approach. Weirich, Gott, and Lillehei described a method of implanting electrodes in the myocardium and stimulating the hearts of patients suffering from surgically induced heart block. Glenn and his associates reported a method of implanting subcutaneously a tuned circuit driven from the outside by a radio-frequency

link. A pacemaker, similar in principle, has been used by Senning. Furman and Robinson reported a method of stimulating patients with complete heart block by passing a catheter into the right ventricular cavity through an accessible vein. In 1959, Hunter and colleagues described a bipolar myocardial electrode. In 1960, Chardack and associates (1) reported the treatment of 3 patients with a totally implanted electronic circuit. A subsequent report by these investigators (2) evaluated their experience with 15 patients.

In a joint effort, the Surgical Research Division of Maimonides Hospital and the Electronics Laboratory of the General Electric Company have developed a totally implantable pacemaker with a fixed minimum rate, as well as the capability of responding to an optional external control.

DESIGN OF THE PACEMAKER

The basic circuit operation consists of a pulse oscillator requiring a small number of components as shown in Figure 1. It employs a PNP or complementary transistor configuration exhibiting a negative resistance across the terminal of resistance $R1$. The theory of such a circuit has been described previously by Suran.

The circuit operation may be summarized as follows: When the capacitor C is completely discharged, the transistor configuration becomes regenerative and acts as a closed switch. The capacitor C is charged from the batteries $E1$ and $E2$ with a time constant given by the product of C and the sum of the load resistance, i.e., the heart,

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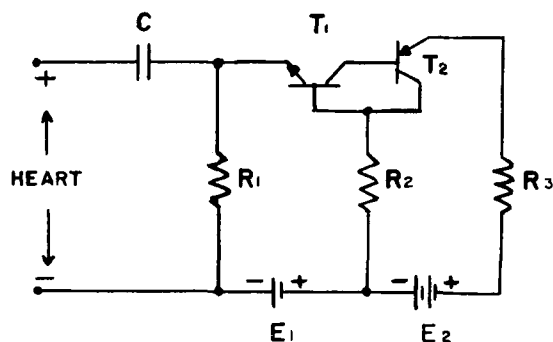


FIG. 1. Circuit diagram of implantable pacemaker.

transistor saturation resistance, and R_3 . The corresponding current surge constitutes the impulse delivered to the heart. When the capacitor voltage reaches the battery voltage ($E_1 + E_2$), the switch turns off and the transistors cease to conduct current. The capacitor C now discharges through R_1 and the load, until C is almost empty, whereupon a new current surge generates another impulse.

The performance of 2 versions of the circuit, one employing 4 and the other 5 mercury cells at 1.4 volts each, is summarized in Table I.

On the basis of the rated capacity of the batteries the implantable pacemaker should operate for at least 5 years without battery replacement. A decrease in battery voltage will, however, result in a change in pulse rate and may, therefore, readily be detected.

TABLE I.

	Circuit A, 4 batteries	Circuit B, 5 batteries
Peak pulse power, milliwatts...	32	56
Peak output voltage, volts....	2.8	3.9
Average current drain, microamperes.....	14	25
Average power drain, microwatts.....	82	184
Energy delivered to the load, microjoules.....	23	64
Power efficiency, per cent....	30	30
Frequency, per minute.....	62	62
Pulse time constant, milliseconds.....	1.8	2
Frequency stability, per cent..	6 between 0 and 60°C.	
Expected battery life, hours—1,000 MA hr. rated capacity.....	71,000	40,000
Packaged volume, including batteries, cubic inches.....	2.4	4

The entire implantable pacemaker circuit was potted in epoxy resin and is shown in Figure 2, together with the external control circuit. The circuit is then hermetically sealed in a teflon case. The load terminals are connected to a pair of teflon-coated, 24 inch long cardiac electrodes. Each electrode consists of 49 braided strands of 1.5 mil annealed No. 316 stainless steel wire. An external control circuit capable of transmitting a suitable trigger pulse to the internal pacemaker has also been developed. This circuit employs a PNP complementary transistor configuration connected in a relaxation oscillator mode similar to the implantable circuit described before. A sharp current pulse is generated which energizes an induction coil and thus triggers the internal circuit magnetically. The minimum and maximum rate of the external control circuit is adjusted by selecting 2 resistors. With a variable resistance, continuous external rate control between the limits of 60 and 120 is then possible. The flat induction coil has a diameter of 3.5 inches and is connected to the circuit by a 15 inch cable. This arrangement permits the patient to attach the coil to the skin close to the internal pacemaker. The area of the coil is considerably larger than that of the internal unit. This discrepancy in size allows the 2 units to be placed up to 1.5 inch off center.

In connection with the development of the pacemaker circuit, measurements were made on 3 patients to determine the nature and quantity of the required electrical stimulation. Stimulation was achieved through a pair of electrodes implanted in the myocardium approximately 1 centimeter apart. The teflon-coated electrodes were brought out of the body for external stimulation. At the time these measurements were made the patients had been stimulated for 6 months. Although the magnitude of the required stimulation increased during the initial period after implantation of the electrodes, the critical threshold levelled off at a constant value.

An electrocardiograph was used as a monitor to indicate whether or not stimulation was achieved. For a number of pulse widths, ranging from 0.3 to 7 milliseconds, the current and voltage waveforms corresponding to the minimum stimulation were photographed. A study of the waveforms permits a determination of the approximate impedance of the load, i.e., the heart, and this was found to consist of a series combination of 300 ohms and 20 microfarad capacitance. The resulting waveforms may then be analyzed in detail in a graphic procedure. The average current, the root-mean-square current, the charge, and the energy of each pulse were determined.

A comparison of the various quantities as a function of pulse width indicates that both current and charge are strongly dependent on pulse width, whereas energy is fairly constant. The data indicate that the nature of the threshold has the dimension of a constant energy level of approximately 15 microjoules per pulse when measured over a fairly wide range of pulse widths. Our findings of the energy requirements of 15 microjoules to stimulate the human heart after 6 months of stimulation through implanted electrodes agree with the findings of Chardack and other workers. It would appear then that this is close to the upper limits of energy required after long term stimulation. Since our unit delivers 64 joules there is a safety factor of close to 400 per cent.

OPERATIVE TECHNIQUE

The operative procedure is carried out under general anesthesia with an endotracheal tube in place. All patients are brought to the operating room under electronic control of an external pacemaker with a cardiac catheter electrode passed through the right saphenous vein. Electrocardiographic leads are then attached to the arms and legs, and the continuous electrocardiogram is displayed on an oscilloscope. The patient is placed in the dorsal recumbent position.

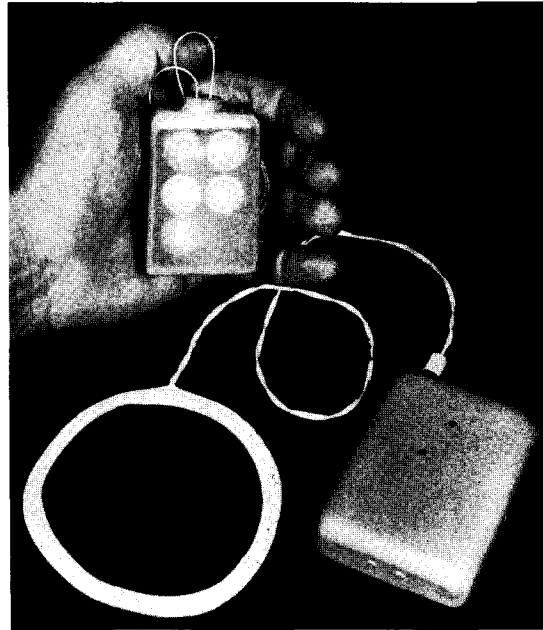


FIG. 2. Five battery implantable pacemaker. Optional external control circuit is on the right.

Two incisions are made. One is a transverse incision of 5 centimeters just to the left of the umbilicus and deepened to the anterior rectus sheath. The second is a left submammary incision. The pleural cavity is entered through the fourth intercostal space. The pericardium is opened to expose the left ventricle. A subcutaneous tunnel is then made from the chest incision to the abdominal incision. The electrodes are individually brought through the tunnel into the chest incision and through the pericardium. Each electrode is sutured into the myocardium, fixing the teflon in the depths of the muscles. The bared electrode is then passed back through the myocardium to emerge near the entrance of the teflon. The second electrode is implanted in the same fashion as the first, 1 centimeter away. The pericardium is closed with interrupted silk sutures. The chest is closed in layers. The pacemaker is then placed into the subcutaneous pocket. Sutures are taken through the teflon coating to attach the pacemaker firmly to the anterior rectus sheath. The subcutaneous tissue and skin

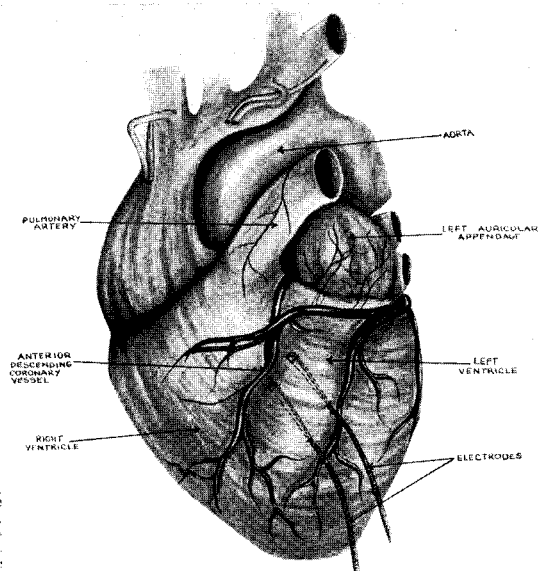


FIG. 3. Drawing of heart with electrodes in left ventricular myocardium.

are closed. The external control unit is taped on the abdomen and set between 80 and 90 per minute.

RESULTS

In our series of 14 patients, 13 had coronary artery disease and 1 patient was believed to have had a viral myocarditis. The indication for implanting the pacemaker in 13 of these patients was multiple Stokes-Adams seizures which did not respond to vigorous medical therapy. In 1 patient the main indication for implanting the pacemaker was congestive heart failure secondary to intractable bradycardia. Implantation of the pacemaker greatly relieved the congestive failure. In 10 patients the mechanism for the Stokes-Adams seizures was ventricular asystole, whereas in 2 patients paroxysmal ventricular tachycardia was the mechanism. One patient had electrocardiographic evidence of varying asystole and ventricular tachycardia.

In the 14 patients in whom this pacemaker has been implanted, there has been no failure of the pacemakers. In Patient 1, 3 months after operation one of the electrodes pulled out of the myocardium and

also frayed at the exit from the pacemaker. Each of these technical problems was corrected, and the patient has been asymptomatic for 6 months. Patient 2 died on the fourth postoperative day from acute pulmonary edema. Autopsy revealed diffuse coronary artery disease but no evidence of acute infarction. In Patient 5 one of the electrodes broke because of a sharp flexion. This problem was solved by implanting a new pacemaker and welding the new electrodes to the old ones going to the heart which avoided another thoracotomy. In Patient 7 congestive failure developed 4 weeks after operation. This condition responded to medical therapy and increasing the heart rate with the external circuit. Patient 11 died on the third postoperative day. This patient, in addition to multiple seizures had diabetic retinopathy, advanced generalized arteriosclerosis, hypertension, and congestive heart failure. Autopsy revealed acute myocardial infarction with advanced coronary sclerosis and advanced arteriolonephrosclerosis. In 12 patients the pulse rate has remained under continuous control since implantation of the pacemaker.

DISCUSSION

The implantable, self-powered pacemaker offers a number of advantages over other types of electronic pacemakers. It eliminates the problems of skin excoriation, infection, and accidental dislodgment of the electrodes of the pacemaker. The electrical energy requirement of an internal pacemaker is a fraction of that required by an external pacemaker. With the internal pacemaker, the patient is not concerned with its control.

The implanted pacemaker has an intrinsic rhythm which is set between 60 and 65 pulses per minute. This rate represents a compromise between a lower rate which would yield longer battery life and a higher rate in which cardiac output would be increased with a diminished stroke volume.

The unit measures approximately 2 by 4 by 6 centimeters. None of the patients has

complained of any discomfort from the subcutaneously implanted pacemaker.

The 9 components were chosen for their compatibility and function well below their rated specifications. Silicon transistors were used rather than germanium, because of their greater reliability. The assembled units were extensively tested in the laboratory by the engineering group, at times trying the patience of the clinical group.

The entire unit has been embedded in teflon. Harrison and associates have shown that teflon is chemically inert and less wettable and incites less tissue reaction than any of the plastics thus far studied. Methods for resealing the teflon in the operating room have been designed should this be necessary to replace the pacemaker or an electrode. This procedure has been carried out successfully in 2 of our cases.

The problem of electrode breakage in Patients 1 and 5 is similar to that reported by other workers. Mechanical problems with the electrodes were re-examined by the Electronics Laboratory of the General Electric Company. It is known that wires implanted in the myocardium are subjected to a certain amount of cyclical stress. A technique was devised to reduce their stress. The electrodes are passed into the myocardium fixing the teflon in the depths of muscle. The bared electrode is then passed back through the myocardium to emerge near the entrance of the teflon. In addition, the exit point of the pacemaker was redesigned so that the electrode is not permitted any point of sharp flexion close to the pacemaker.

The external control circuit is an optional, transistorized device that the patient wears when it seems desirable for him to have an increased pulse rate. We have found this to be a distinct advantage in several situations. All 14 patients were sent from the operating room to the recovery room with the external control circuit setting the implanted pacemaker at a rate between 80 and 100 beats per minute. It is also desirable to increase the pulse rate during periods

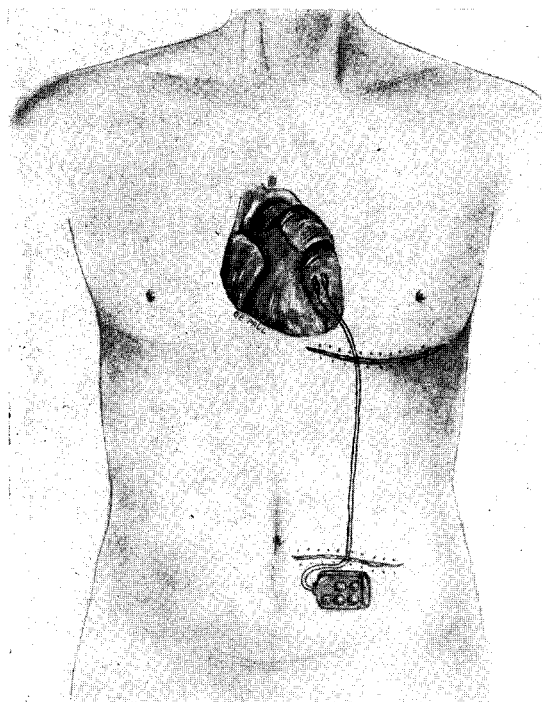


FIG. 4. Illustration of incisions and sites of implantation of pacemaker and electrodes.

of stress such as infection, blood loss, and exercise. Younger patients have found it desirable to have the ability to increase their pulse rate during vigorous exertion.

Finally, the functioning of the implanted pacemaker can be studied by using the external control circuit as a test instrument. It has been shown that failure of the internal pacemaker to follow the external control circuit at a rate of 120 indicates increasing myocardial threshold or decreasing energy levels being delivered by the internal pacemaker.

The clinical use of implanted pacemakers has an additional significance. It represents a departure from the conventional role of medical electronics in measuring and gathering data. With engineering achievements such as microminiaturization and circuits requiring low power, an important new role for electronic devices can be foreseen. We have used the word "bioelectronics" to describe this integrated, long term electronic control of various impaired physi-

ologic systems. We (7) and others have reported explorations in this cross-discipline which holds exciting promise for the future.

SUMMARY

1. An implantable, transistorized, self-powered, teflon-encapsulated, electronic circuit capable of serving as an artificial pacemaker for patients suffering from intractable Stokes-Adams seizures is described.

2. Clinical experience with 14 patients has been encouraging. One patient died 4 days after operation from acute pulmonary edema, and autopsy revealed extensive coronary artery disease. Another patient died 3 days after operation, and autopsy revealed acute myocardial infarction and advanced arteriolonephrosclerosis. Two patients suffered from electrode breakage. This failure of the electrodes was corrected by modified techniques.

3. The advantages of this unit are its high reliability, small size, and low power drain. It is responsive to an optional external circuit which may be used when higher rates are desired.

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